as mentioned above except the type of ethylcellulose used.

A dissolution study of the coated crystals and tablets was performed in deionized water.

The following table is a summary of the dissolution test:

TABLE II

	CUMULATIVE % KCl RELEASED				
	1 hr	2 hr	4 hr	6 hr	Ethocel ® Type
Coated Crystals	33	52	78	94	Ethocel ® 10
Tablets	52	69	86	97	
Coated Crystals	27	59	84	95	Ethocel ® 100
Tablets	26	55	83	94	

In accordance with a preferred embodiment of the present invention potassium chloride tablets containing 1500mg of potassium chloride are prepared. The potassium crystals form about 68% to about 86.5% by weight of these tablets and are coated with ethylcellulose (preferably Ethocel ® 100) in an amount in the range of 9 to 15% by weight based on the weight of the micro pellets formed with the potassium chloride crystals; 0.5 to 3% by weight of hydroxypropylcellulose based on the weight of the micro pellets; 0.5 to 2% by weight of magnesium stearate based upon the weight of the tablet; 3 to 10% by weight of microcrystalline cellulose based upon the weight of the tablet; 0.5 to 2% by weight crospovidone based upon the weight of the tablet.

Within each of these ranges it is particularly preferred for the 1500 mg tablets to include 79 weight percent of potassium chloride, 11.9% by weight of ethylcellulose (preferably Ethocel ® 100), 1.4% by weight hydroxypropylcellulose, 0.7% by weight of magnesium stearate, 6% by weight of microcrystalline cellulose and 1% by weight of crospovidone.

In accordance with the present invention a clinical batch of 1500 mg tablets of potassium chloride were prepared. The tablets were comprised as shown in the following Table III.

TABLE III

POTASSIUM CHLORIDE S.R. TABLETS
20 mEq
QUANTITATIVE LIST OF COMPONENTS

QUANTITY/ TABLETS	INGREDIENTS	QUANTITY/ BATCH	% WT.
(20 mEq) 1500 mg	Potassium Chloride, USP	255.00 kg	79.0
225 mg	Ethylcellulose, NF (Ethocel ®, Type 100)	38.25 kg	11.9
27 mg	Hydroxypropylcellulose, NF (Klucel ®, L.F.)	4.50 kg	1.4
13 mg	Magnesium Stearate, NF	2.25 kg	0.7
114 mg	Microcrystalline Cellulose, NF (Avicel ® PH 101)	19.36 kg	6.0
19 mg	Crospovidone, NF (Polyplasdone XL)	3.23 kg	1.0
*	Methyl Alcohol, NF (Methanol)	168.65 kg	*
*	Methylene Chloride, NF	846.45 kg	*
1898 mg	TOTALS	322.59 kg/ 170,000 Tablets	

* Removed during processing.

COMPARATIVE EXPERIMENT

In order to demonstrate the safety of the present invention, a clinical study was carried out which compared potassium chloride tablets (20 mEq) produced in accordance with the present invention with four commercial products as follows: Slow-K ® (a sugar-coated wax matrix tablets from Ciba); Micro-K Extencaps ®, (capsules of crystalline KCl particles coated with polymer from A. H. Robins); Kaon ® Elixir (liquid potassium gluconate), and placebo.

In this particular investigator blinded study comparing the 20 mEq KCl tablets to 4 standard preparations in a dose of 80 mEq per day, no serious endoscopic lesions were found with the tablet of the present invention. Overall, the safety of the tablet was equal to or better than any of the comparative agents.

The present invention has been disclosed and described herein in what is considered to be its most preferred embodiments. It should be noted that variations may occur to those skilled in the art upon reading the present disclosure and that such variations are intended to come within the scope of the present invention.

What is claimed:

1. A pharmaceutical dosage unit in tablet form for oral administration of potassium chloride, comprising;

a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 64% to about 86.5% by weight based on the total weight of the dosage unit;

a coating material for the individual potassium chloride crystals, the coating material comprising ethylcellulose in the amount in the range of about 9% to about 15% by weight based on the total weight of the coated crystals and at least one member selected from hydroxypropylcellulose and polyethylene glycol in an amount in the range of about 0.5% to about 3% by weight based on the total weight of the coated crystals and said ethylcellulose has a viscosity greater than 40 cp.

2. A pharmaceutical dosage unit as claimed in claim 1, wherein the tablet is further comprised of magnesium stearate in an amount in the range of about 0.5% to 2.0% by weight based on the total weight of the tablet.

3. A pharmaceutical dosage unit as claimed in claim 2, wherein the tablet is further comprised of a microcrystalline cellulose in an amount in the range of about 3 to 10% by weight based on the total weight of the tablet.

4. A pharmaceutical dosage unit as claimed in claim 3, further comprising cross-linked polyvinylpyrolidone in an amount in the range of about 0.5 to about 2.0% by weight based on the total weight of the tablet.